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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,265	11/13/2001	Allen Carl	49386-CIP(71995)	1326
21874	7590	03/24/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			PRIDDY, MICHAEL B	
		ART UNIT		PAPER NUMBER
		3732		7

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/019,265	CARL ET AL. <i>On</i>
<b>Examiner</b>	<b>Art Unit</b>	
Michael B Priddy	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 73-153 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 73-105, 107-120, 132-135 and 153 is/are allowed.
- 6) Claim(s) 121-125, 127, 128, 136, 138 and 149 is/are rejected.
- 7) Claim(s) 106, 126, 129, 130, 131, 137, 139-148 and 150-152 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claim 106 is objected to because of the following informalities: in line 3, "collogen" should be --collagen--. Appropriate correction is required.

Claim 121 is objected to because of the following informalities: in line 4, "vertebrate" should be --vertebrae--.

Claims 131 and 137 are objected to because of the following informalities: in line 2, "that passes through" should be --received in--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 121-123 and 149 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 121, lines 2-3, applicant positively recites part of a human, i.e. "a mammalian spine with a surgically implanted arcuate member and an intervertebral prosthetic device". Thus claims 121-123 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 121, 122, 124, 125, 127, 128, 136 and 138 are rejected under 35 U.S.C. 102(b) as being anticipated by Steffee (U.S. 4,790,303). Steffee teaches an apparatus for securing a bone graft comprising: an intravertebral prosthetic device 24; an arcuate implant member 50/52/70 of a size sufficient to extend between two adjacent vertebrae; wherein the intravertebral prosthetic device 24 is configured to receive therein a portion 50/52 of the arcuate implant member 50/52/70; and wherein the implant member 50/52/70 is sized so as to extend through a pre-formed aperture in each of the two adjacent vertebrae; wherein the arcuate implant member 50/52/70 is configured and sized so as to be a load bearing member.

Concerning the language "configured and sized so as to be a load bearing member", it is noted that in order for a reference to meet this limitation it need merely disclose structure capable of performing this function. It is the Examiner's position that the arcuate member of Steffee, particularly the fasteners 50 and 52, do bear a tensile load against which they are intended to fix device 24 and adjacent vertebrae 22 and 26.

Concerning the language "sized so as to extend through a pre-formed aperture in each of the two adjacent vertebrae", it is noted that in order for a reference to meet this limitation it need merely disclose a structure capable of performing this function. It is the Examiner's position that members 50 and 52 taught by Steffee, while intended to be

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used without preformed apertures, could certainly be used through pre-formed apertures as well.

Finally concerning the language of claim 125, "wherein the preformed aperture in each of the adjacent vertebrae is of a constant radius and wherein the arcuate implant member is configured so as to extend through each of the constant radius preformed aperture", it is noted that claim 124 does not appear to require "a pre-formed aperture in each of the two adjacent vertebrae" since this structure is only functionally recited and would not be patentable since it would include part of a human "in each of the two adjacent vertebrae" within its scope. Therefore, Steffee need only disclose an arcuate implant member capable of extending through a preformed aperture of constant radius. It is the Examiner's position that the device taught by Steffe is indeed capable of this.

***Allowable Subject Matter***

Claims 106, 131 and 137 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 126, 129, 130, 139-148 and 150-152 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 73-105, 107-120, 132-135 and 153 are allowed.

***Response to Arguments***

Applicant's arguments and amendments with respect to claims 73-120 are persuasive and have overcome the rejections included in the Office Action of 08/01/2003. No specific arguments by Applicant were directed to the allowability of the newly added claims 121-153 and the Examiner therefore believes the patentability of these claims has been sufficiently addressed in other portions of the present Office Action.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

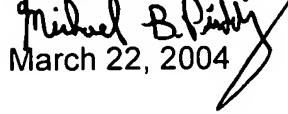
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

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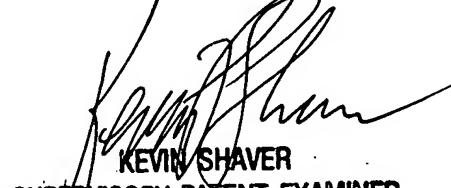
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy

  
Michael B. Priddy

March 22, 2004

  
KEVIN SHAVER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700